

OBJECTIVES: The Ontario Drug Policy Research Network has received provincial government funding to conduct research relating to formulary modernization within the Ontario Public Drug Programs. This innovative, integrated program for drug class reviews incorporates a novel methodological technique called reimbursement-based economics which focuses on reimbursement strategies. The first class review related to triptans for migraines. In Ontario, triptans are currently available through the Exceptional Access Program (EAP). Specific research questions related to the current evidence for the cost-effectiveness of triptans and the economic impact of alternative changes to their funding status. **METHODS:** Systematic review of cost-effectiveness studies of triptans focusing on strength and quality of evidence. 2. Applied, policy-oriented reimbursement based economic model developed to forecast budget expenditure for each alternative reimbursement strategy (generic pricing, generic substitution, quantity limits and/or more liberal access). **RESULTS:** 21 economic studies were identified though many had a number of common limitations reducing their usefulness in aiding decision making. The weight of evidence suggests that triptans are more cost effective than ergots, in patients experiencing acute migraine. Maintaining triptans within the EAP with generic equivalents costing 25% of branded products reduces expenditure by 18%-85%. Greater access to triptans but with a quantity limit of 6 units per month would increase total expenditure by between 133%-140%; less restrictive quantity limits would lead to expenditure increases of up to 326%. **CONCLUSIONS:** Evidence suggests that, for migraine, triptans are cost effective compared to ergots. Allowing greater access to triptans would significantly increase expenditure and may lead to use in a wider population where neither effectiveness nor cost effectiveness has been established. Maintaining triptan coverage through EAP with generic equivalents costing 25% of branded products combined with generic substitution will reduce total expenditures by 67%. Other factors will be considered before final recommendations on formulary changes are made.

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AND THEN THERE WERE THREE; THE BURGEONING MARKET OF ORAL MEDICATIONS APPROVED TO TREAT MULTIPLE SCLEROSIS IN THE UNITED STATES

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OBJECTIVES: The first oral disease modifying therapy (DMT) was approved in the fall of 2010, the second followed two years later with a short six-month gap before the third approval. This study sought to describe and compare patients prescribed one of the three oral DMTs available to treat relapsing forms of multiple sclerosis (MS) in the US. **METHODS:** Adult patients with a claim for fingolimod, terifunomide or dimethyl fumarate on or after September 22, 2010 ('index') were identified in the Truven Health MarketScan® databases. Patients had an MS diagnosis (ICD-9-CM 340) in the 12 months prior to index, continuous enrollment 12 months pre- and 3 months post-index and a confirmatory claim for their index drug. Demographic, clinical and severity characteristics were measured and compared in the 12 month baseline period. **RESULTS:** A total of 3,379 patients were included, mean age 46.3 (SD 10.5), 75.4% female. The majority (85.8%, n=2,899) indexed on fingolimod, with 10.0% (n=339) indexing on terifunomide and the remaining 4.2% (n=141) indexing on dimethyl fumarate. Patients indexing on terifunomide and dimethyl fumarate were significantly older than those indexing on fingolimod (50.0 [SD 9.6] and 48.1 [SD 10.4] vs. 45.8 (SD 10.2), respectively, both p<0.01). A greater proportion of patients indexing on terifunomide had chronic pain, high blood pressure and high cholesterol than those indexing on fingolimod (47.2% vs. 40.8%, 30.4% vs. 19.7% and 24.5% vs. 15.8%, respectively, all p<0.05) and a greater proportion of patients indexing on dimethyl fumarate had arthritis and thyroid disease than those indexing on fingolimod (13.5% vs. 6.9% and 13.5% vs. 8.1%, both p<0.05). **CONCLUSIONS:** Factors in the decision to start disease modifying therapy with one of the oral medications can be complex. This study showed that older patients with more comorbid disease are being channeled to the two newest oral medications on the market.

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CLINICAL PRACTICE OF INTRATHECAL DRUGS FOR MANAGEMENT OF PAIN AND SPASTICITY: A MULTINATIONAL CROSS-SECTIONAL SURVEY OF HEALTH CARE PROVIDERS

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OBJECTIVES: Intrathecal drug therapy via implanted pump for treatment of spasticity and chronic pain is highly varied and may have significant implications for patient outcomes. The objectives of this study were to: 1) characterize factors that influence real-world usage of these drugs, and 2) identify key differences and similarities in clinical practice, along with unmet needs across global markets. **METHODS:** A cohort of 96 health care providers (HCPs) was surveyed across 6 countries, Canada (16), France (15), Italy (10), Germany (20), UK (15), and US (20). The HCPs included physicians and nurses caring for patients with intrathecal pumps across multiple specialties. **RESULTS:** Compounded vs Manufacturer-prepared: While respondents cited continued need for compounded drugs (66%), comparable manufacturer-prepared drugs, if available, were preferred by at least 33% (highest in Germany, 45%), even at a higher procurement cost (20%). Over 25% respondents expressed concern over compounded drugs, including limited regulation, variable efficacy, and potential for sterility issues. 1) Dosage: Depending on the drug, from 60% to 90% of respondents expressed interest in new manufacturer-prepared doses; 2) Packaging Format: Over 77% respondents preferred pre-filled syringes over ampules (18%) or vials (5%), largely due to ease of use and sterility. Despite this preference, 65% of respondents were concerned about the associated higher cost of pre-filled syringes. **CONCLUSIONS:** This cross-sectional survey identified consistent themes across the 6 markets. Unmet needs identified included opportunities for manufacturer-prepared drugs, new packaging forms, and new concentrations.

Overall, clinicians' preferences for drugs delivered via intrathecal pumps were driven by patient-related health factors.

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BARRIERS TO PRESCRIBING MEDICATIONS TO PATIENTS WITH MULTIPLE SCLEROSIS: A COMPARISON OF HEALTH CARE PROVIDER PERCEPTIONS IN EUROPEAN UNION (EU) AND THE UNITED STATES

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OBJECTIVES: To assess health care provider (HCP) perception of barriers to prescribing medications to patients with Multiple Sclerosis (MS) in EU and the US. **METHODS:** A multi-country HCP survey was conducted in 5EU (UK/Germany/France/Spain/Italy) and the US as part of a retrospective chart-review study of MS patients. HCPs (mostly physicians) were screened for experience (>=3yrs) and patient volume (>15MS patients/month) and recruited from a large HCP-panel to be geographically representative in each country. Practice characteristics, HCP perceptions and practice patterns were assessed. HCP perceptions of the following barriers to prescribing interferons (all types), glatiramer acetate, natalizumab and fingolimod were assessed: patients prefer other medications (barrier-1), availability/cost (barrier-2), guidelines/license restrictions (barrier-3) and drug-related issues (barrier-4). Summary statistics are reported. **RESULTS:** In 4Q2012, 360 HCPs (neurologists:95%; nurses:5% (from UK only)) participated. Mean age (5EU/US):45/50yrs; female (5EU/US):34%/21%; years practicing in neurology (5EU/US):16/19yrs; practice-location (>=50% of time in hospital-setting, 5EU/US):83%/26%; % HCPs seeing MS patients in specialty clinic (5EU/US):53%/27%; % HCPs with MS as the main focus area (5EU/US):68%/40%. Geographic distribution of HCPs was: 5EU-72% (UK-16%, Germany/France/Spain/Italy-14% each), US-28%. Patient volume/month per HCP was (5EU/US): All-patients-254/319, MS-patients-61/68. MS patient-type seen was (5EU/US): relapsing-remitting-52%/58%, relapsing secondary progressive-13%/13%, non-relapsing secondary progressive-13%/12%, primary progressive-8%/6%, clinically isolated syndrome-9%/7%, benign-6%/4%. Average prescriptions written/month for MS-treatments was (5EU/US):51/62. Key barriers to prescribing interferons were (5EU/US): barrier-1:12%/13%, barrier-2:11%/21%, barrier-3:9%/8%, barrier-4:55%/56%, no-barrier:30%/24%; for glatiramer (5EU/US): barrier-1:14%/12%, barrier-2:9%/18%, barrier-3:8%/6%, barrier-4:62%/60%, no-barrier:28%/28%; for natalizumab (5EU/US): barrier-1:16%/17%, barrier-2:28%/36%, barrier-3:47%/23%, barrier-4:81%/92%, no-barrier:15%/5%; for fingolimod (5EU/US): barrier-1:5%/21%, barrier-2:35%/48%, barrier-3:49%/21%, barrier-4:65%/84%, no-barrier:17%/4%. **CONCLUSIONS:** Drug-related issue was the most frequently cited barrier to prescribing MS medications both in 5EU and the US. Drug availability/cost and guidelines/license restrictions were more often cited by HCPs in the US and 5EU respectively. Impact of these barriers on optimal patient management and outcomes may warrant further research.

PND58

PAYER MANAGEMENT OF ORAL MULTIPLE SCLEROSIS THERAPIES IN UNITED STATES

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OBJECTIVES: The purpose of this study was to understand how United States payers manage novel oral, high cost MS medications in consideration of the availability of lower cost injectable treatments, generally considered less convenient regarding administration while in line with the efficacy of orals. **METHODS:** The respective tier statuses and utilization management of terifunomide, fingolimod, dimethyl fumarate, interferon beta-1a (AVONEX and REBIF), and glatiramer acetate at 46 plans were audited: 18 Medicare, 12 national private (including PBMs), and 16 regional and state private plans. Access to oral MS treatments was compared to that of injectable MS treatments to identify differences in tiering or utilization management. **RESULTS:** 54% of plans demonstrated preferential coverage of injectable MS therapies over orals, by lower tier status or lighter utilization management. By segment, regional and state private plans demonstrated the strongest preference for injectables, with 75% of these plans demonstrating this preference compared to 50% of Medicare and 33% of national private plans. Plans employing prior authorization or step edits to manage oral MS therapies usually stepped orals through injectables. Among oral MS products, national private and Medicare plans tended to prefer fingolimod, with 50% and 61% of plans preferring it over at least one other oral MS product, respectively. 19% of regional and state private plans preferred dimethyl fumarate over at least one other oral MS product. **CONCLUSIONS:** United States payers take varying approaches to the management of oral MS medications; however, virtually no plans offer preferential access to orals over injectables. The sample is roughly split between plans preferring injectable MS products over orals and those offering roughly parity access.

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CLEFT LIP SURGERY: RESULTS FROM THE KIDS' INPATIENT DATABASE

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OBJECTIVES: Cleft lip with and without cleft palate is the second most prevalent birth defect in the United States. Previous epidemiological studies of cleft lip surgery have been plagued by multiple design and methodological issues, including failure to adjust costs, grouping of cleft lip only (CL) with cleft lip and palate (CLP) diagnoses, and improper definition of secondary cleft lip surgery. The objective of this study was to provide national estimates of primary and secondary cleft lip surgery using cohort definitions based on national treatment guidelines. **METHODS:** The nationally representative Kids' Inpatient Database (KID) was used for this study. Years analyzed included 2003, 2006, and 2009. Subjects were identified by International Classification of Diseases Ninth Revision (ICD-9) diagnosis of cleft lip only or cleft lip and palate. Primary surgery was defined as a surgery before two years of age with the ICD-9 procedural code for cleft lip repair. Secondary surgery was defined as a sur-